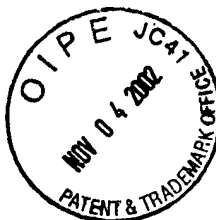


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BART S. HERSKO	32,572	
Name of Attorney/Agent	Registration No.	
<i>Bart S. Hersko</i>		
Signature of Attorney		

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE  
RESPONSE/AMENDMENT**

Case Docket No. 7606R

Box Non-Fee Amendment  
ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

Dear Sir:

Transmitted herewith is an AMENDMENT for the patent application:

Inventor(s): Yuzhakov et al. Confirmation No. 9337

Serial No.: 09/580,819 Group Art Unit: 3762

Date Filed: May 26, 2000 Examiner: Michael M. Thompson

Title: Intracutaneous Microneedle Array Apparatus

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TECHNOLOGY CENTER PC700

1. ☒ No additional fee is known to be required.
2. ☐ The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)	OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA*	RATE	FEE
TOTAL	*	MINUS	**	=	x \$18 =	\$
INDEP.	*	MINUS	***	=	x \$84 =	\$
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ \$280 =	\$
					TOTAL	\$0

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the highest number of total claims previously paid for is less than 20, write "20" in this space.

\*\*\* If the highest number of independent claims previously paid for is less than 3, write "3" in this space.

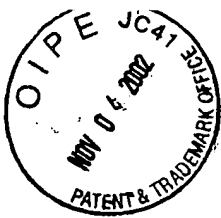
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

3. ☐ The Commissioner is hereby petitioned under 37 CFR §1.136(a) to grant any extension of time needed for timely response to the Office Action dated in the above-identified application to preserve pendency of said application. The processing fee under 37 CFR §1.17 has been determined as follows: \$ for a -month extension of time.
4. The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-2480. A duplicate copy of this sheet is attached.
  - a. ☒ Any patent application processing fees under 37 CFR §1.16.
  - b. ☒ Any patent application processing fees under 37 CFR §1.17.
5. The Commissioner is hereby authorized to make any additional copies of this sheet needed to accomplish the purposes provided for herein and to charge any fee for such copies to Deposit Account No. 16-2480.

*Bart S. Hersko*

Bart S. Hersko  
Attorney for Applicant(s)  
Registration No. 32,572  
Tel. No. (513) 634-9135

October 30, 2002  
Customer No. 27752



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Bart S. Hersko 32,572  
Name of Attorney Registration No.  
*Bart S. Hersko*  
Signature of Attorney

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Case 7606R

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of :  
**YUZHAKOV ET AL.** :  
Serial No.: 09/580,819 : Group Art Unit: 3762  
Filed: May 26, 2000 : Examiner: Michael M. Thompson  
Confirmation No. 9337

For: **INTRACUTANEOUS MICRONEEDLE ARRAY APPARATUS**

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**RESPONSE TO RESTRICTION AND  
ELECTION OF CLAIMS REQUIREMENTS**

TECHNOLOGY CENTER P3700

Box Non-Fee Amendment  
Assistant Commissioner for Patents  
Washington, D. C. 20231

Dear Sir:

In an Office Action mailed on October 1, 2002, the Examiner has imposed a restriction requirement as between a first species "A" involving Figure 22, a second species "B" involving Figure 34, and a third species "C" involving Figures 35-36. In addition, the Examiner has required Applicants to elect a single sub-species relating to either a "hollow" needle, or a "solid" needle.

**List of Species, and Corresponding Description:**

- Species A — a hollow "edged" microneedle, with two sharp extensions along its side walls from the top to the bottom of the microneedle; this embodiment is illustrated in both Figures 32 and 33.
- Species B — a hollow "edged" microneedle, with two sharp extensions along its side walls from the top toward the bottom, in which the sharp edge does not extend completely to the bottom of the microneedle; this embodiment is illustrated on Figure 34, as noted by the Examiner.

Species C — a non-hollow (or solid) "edged" microneedle, with three sharp extensions that form side "walls" or "blades," in which the blades extend from the top to the bottom of the microneedle; as noted by the Examiner, this embodiment is illustrated in both Figures 35 and 36.

**List of Claims and Corresponding Species:**

Claim 1: A, B, C	Claim 11: C	Claim 21: C
Claim 2: A, B	Claim 12: A, B, C	Claim 22: C
Claim 3: A, B	Claim 13: A, B, C	Claim 23: C
Claim 4: A, B	Claim 14: A, B	Claim 24: A, B, C
Claim 5: A, B	Claim 15: A, B	
Claim 6: A, B	Claim 16: A, B	
Claim 7: A, B	Claim 17: A, B	
Claim 8: C	Claim 18: A, B	
Claim 9: C	Claim 19: A, B	
Claim 10: C	Claim 20: C	

**Discussion of Species:**

The restriction requirement in this application is respectfully traversed, as the independent claims cover virtually all forms of microneedles, regardless as to whether they are hollow or solid, or whether or not they have "sharp" edges. The figures called out by the Examiner in the Restriction Requirement have nothing to do with the primary elements of the claims, since these figures clearly illustrate a specific style of microneedle that exhibits "sharp" edges along its side walls, whereas the instant claims have limitations that specify a "separation distance" range and a "length" range. It is true that most of the dependent claims specify a microneedle style of either "hollow" or "solid," and Applicants will provisionally elect one of those styles as a sub-species below.

It should be noted that the claims of this application are directed to microneedle structures that extend well past the embodiments illustrated in Figures 32-36, and thus the independent claims should be considered generic claims. As noted above, the independent claims of this application do not incorporate limitations of "sharp" edges, or any other type of "shape" or "profile." Of course, certain dependent claims specify that the "projections" are hollow (for claims 2-7, and 14-19), or solid (for claims 8-11, and 20-23). This fact should be apparent from the listing provided above of claims vs. species.

Since the Examiner's species A, B, and C are not really appropriate for the claims of the instant application, Applicants must make a provisional election based upon a criterion other than the shapes found in Figures 33-36. As noted above, Applicants will provisionally elect a sub-species with regard to a "style" characteristic as to whether the "projections" are either hollow or solid.

### Conclusion

Applicants have traversed the Restriction Requirement in view of the general nature of the claims of the present application, in that these claims do not recite any limitation about sharp edges along the side walls of the microneedle projections, and are thus not confined to the embodiments of Figures 33-36. Many dependent claims do include a "style" limitation as to being either hollow or solid, and Applicants will make a provisional election below to choose a sub-species, as required by the Examiner. However, Applicants ask the Examiner to reconsider and withhold the Restriction Requirement until after examining the independent claims.

While it is Applicants' position that claims 1-24 should not be subjected to a restriction requirement, in order to comply with 37 C.F.R. 1.146, and the Examiner's requirement, Applicants hereby provisionally elect the "hollow" claims for prosecution on the merits, which are claims 1-7, 12-19, and 24.

Respectfully submitted,

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October 30, 2002  
Customer Number 27752